United States District Court
District of Massachusetts

AMPHASTAR PHARMACEUTICALS, INC. and INTERNATIONAL MEDICATION SYSTEMS, LTD.,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 16-10112-NMG**
MOMENTA PHARMACEUTICALS, INC. and SANDOZ INC.,	)	
Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

This is an antitrust case in which plaintiffs Amphastar Pharmaceuticals, Inc. ("Amphastar Pharmaceuticals") and International Medication Systems, Ltd. ("IMS")(collectively, "Amphastar" or "plaintiffs") allege that defendants Momenta Pharmaceuticals, Inc. ("Momenta Pharmaceuticals") and Sandoz Inc. ("Sandoz")(collectively, "Momenta" or "defendants") restricted trade and prevented competition in the manufacture and sales of the generic drug enoxaparin.

Pending before the Court is Momenta's motion for certification of an interlocutory appeal (Docket No. 159). For the following reasons, that motion will be denied.

I. Procedural Background

This case has followed a long and protracted road to this point. This action was filed in the Central District of California in September, 2015. In December, 2015, Momenta filed a motion to dismiss and a separate motion to transfer the case to the District of Massachusetts based upon "substantial overlap" of issues, claims, witnesses and evidence between the instant case and the prior patent action in this Court. The District Court for the Central District of California allowed the motion to transfer and the case was assigned to this session in January, 2016. Amphastar filed a writ of mandamus to the Ninth Circuit Court of Appeals ("the Ninth Circuit") to revoke the transfer on personal jurisdiction grounds and the Ninth Circuit denied that petition in May, 2016.

In July, 2016, this Court allowed Momenta's motion to dismiss on the grounds that Amphastar's claims were precluded by the Noerr-Pennington doctrine. Amphastar appealed that order to the First Circuit Court of Appeals ("the First Circuit") which reversed the order and remanded the case, directing this Court to consider defendants' alternative arguments for dismissal. In March, 2018, after careful consideration of those arguments, this Court denied defendants' motion to dismiss.

In April, 2018, defendants filed the pending motion for certification of an interlocutory appeal, seeking a (second)

review by the First Circuit of this Court's disposition of their motion.

II. Motion for Certification of an Interlocutory Appeal

A. Legal Standard

District courts may certify an otherwise non-appealable order for interlocutory review by the Court of Appeals if the order 1) involves a controlling question of law 2) as to which there are grounds for a substantial difference of opinion and 3) an immediate appeal would materially advance the ultimate termination of the litigation. 28 U.S.C. § 1292(b); Carabello-Seda v. Municipality of Hormigueros, 395 F.3d 7, 9 (1st Cir. 2005). The First Circuit has emphasized that interlocutory certification "should be used sparingly and only in exceptional circumstances". Carabello-Seda, 395 F.3d at 9. Generally, the First Circuit will not certify interlocutory appeals from a denial of a motion dismiss. Id. Interlocutory appeals may be necessary, however, "in long-drawn-out cases, such as antitrust and conspiracy cases." Milbert v. Bison Lab., 260 F.2d 431, 433 (3d Cir. 1958) (citing House Report No. 1667, 85 Cong. 2d Sess., pp. 1, 2).

B. Application

Momenta contends that interlocutory review is appropriate here to resolve two controlling questions of law. Momenta submits that the First Circuit has not yet considered

(1) whether antitrust liability in the standard-setting context requires that the alleged misconduct cause the standard-setting organization to eliminate alternative technologies and (2) whether antitrust plaintiffs must allege that the standard-setting organization would not have adopted the patented technology but for the defendant's misrepresentation.

Amphastar disputes whether there is a difference of opinion on a controlling question of law. It asserts that the allegations in the complaint are consistent with well-established precedent that deception before a standard-setting organization which leads to the exclusion of competitors can form the basis for antitrust liability. Amphastar emphasizes that (1) the question of whether or not the adoption of the 207 Method by the United States Pharmacopeial Convention ("USP") represented a mandatory method is a factual dispute not appropriate for resolution at the motion to dismiss stage and (2) Momenta's second proposed question on causation is also fact-intensive because it depends on the existence of alternative technologies in the marketplace.

Certification of an interlocutory appeal from a denial of a motion to dismiss is disfavored in the First Circuit. Caraballo-Seda, 395 F.3d at 9 (citing In re Heddendorf, 263 F.2d 887, 889 (1st Cir. 1959) (noting a general preference against "piecemeal" litigation)). In denying Momenta's motion to dismiss, the Court

determined that Amphastar had plausibly alleged that the 207 Method had been made mandatory by the USP's adoption of the method and the FDA's subsequent incorporation of the method into the approval process. The Court noted that the question of whether the method was mandatory, such that it created the requisite lock-in to create antitrust liability under Broadcom Corp. v. Qualcomm, Inc., 501 F.3d 297, 315-17 (3d Cir. 2007), was a fact-intensive question that could not be resolved at the motion to dismiss stage. Amphastar has sufficiently alleged that the adoption of the 207 Method resulted in a lock-in of competitors through the standard-setting process and whether a lock-in did in fact occur will turn on the factual development in the case. See, e.g., Johansen v. Liberty Mutual Grp., Inc., 15-cv-12920, 2017 WL 937712, at *1 (D. Mass. March 7, 2017) ("A controlling question of law usually involves a question of meaning of a statutory or constitutional provision, regulation or common law doctrine rather than an application of law to facts.") (quoting Ahrenholz v. Bd. Of Trs. of Ill., 219 F.3d 674, 676 (7th Cir. 2000)).

With respect to its second proposed question for certification, Momenta maintains that Amphastar was required to allege that alternative technologies existed and were considered by the USP. In denying Momenta's motion to dismiss, this Court held that Amphastar plausibly alleged that it was required to

use the 207 Method to obtain FDA approval and that fact-intensive questions about the "feasibility, availability and even existence" of alternative methods remained. In Broadcom, the Third Circuit Court of Appeals rejected the defendant's contention that specific allegations of an alternative method were necessary to survive a motion to dismiss. Broadcom, 501 F.3d at 315 (noting that although defendant "makes much of the Complaint's failure to allege that there were viable technologies competing . . . for inclusion in the [applicable] standard", the complaint sufficiently pled that the organization's adoption of the standard eliminated competing technologies). As that Court explained, even if the method in question was "the only candidate for inclusion in the standard", the allegations that the method would not be selected but for the relevant alleged deceptive conduct were sufficient to survive a motion to dismiss. Id.

Accordingly, the two issues proposed by Momenta for appeal do not represent controlling questions of law and both involve questions of fact and the application of law to facts. For that reason, certification of an interlocutory appeal would not materially advance the ultimate termination of this litigation and is therefore inappropriate.

ORDER

For the foregoing reasons, defendants' motion for certification of an interlocutory appeal (Docket No. 159) is **DENIED.**

So ordered.

/s/ Nathaniel M. Gorton_____
Nathaniel M. Gorton
United States District Judge

Dated June 1, 2018